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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,595	07/05/2001	Stefanie Sprunck	514413-3885	7610

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EXAMINER

KALLIS, RUSSELL

ART UNIT	PAPER NUMBER
1638	12

DATE MAILED: 01/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/899,595	SPRUNCK ET AL.
	Examiner Russell Kallis	Art Unit 1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.

- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.

- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.

- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 13 November 2002.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-16 is/are pending in the application.

4a) Of the above claim(s) 14 and 16 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-13 and 15 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>8</u>	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, Claims 1-13, and 15 in Paper No. 11 is acknowledged. The traversal is on the ground(s) that there would be no undue burden in examining Groups I-II together because they have the same classification and hence could be searched together. It is noteworthy to reiterate that the inventions of Groups I and Group II were indeed given separate classification. The classification for Group I is in 800/288 and Group II in 800/285. Further, Applicant asserts that SEQ ID NOs: 1-10 cannot be considered patentably distinct because they are functionally related. The nucleotide sequence of SEQ ID NOs: 1-10 are drawn to DNA compositions of discreet length and function. Furthermore, since 1996 resources at the Patent office have changed and the examination and search of more than one sequence would pose an undue burden.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13, and 15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant broadly claims a nucleic acid with the function of a caryopsis-specific promoter of SEQ ID NO: 1; a functional portion of SEQ ID NO: 1; a sequence that hybridizes under conditions of unspecified stringency to SEQ ID NO: 1; a sequence that has between 60-99% sequence identity to SEQ ID NO: 1.

Applicant describes SEQ ID NO: 1 and sequence elements consisting of SEQ ID NO: 2-10.

Applicant does not describe caryopsis-specific promoters with 60-99% sequence identity to SEQ ID NO: 1 or any sequences that hybridize to SEQ ID NO: 1, other than the promoter of SEQ ID NO: 1; or any sequences other than SEQ ID NO: 1 that comprise one or more sequence elements selected from the group consisting of SEQ ID NO: 2-10.

Given the claim breadth and lack of guidance as discussed above, the specification does not provide an adequate written description of the claimed invention.

See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

The court also addressed the manner by which genus of cDNAs might be described: “A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.” *Id.* At 1406.

Given the failure of the caryopsis-specific promoter DNA to be adequately described, methods of its use are also inadequately described. See Written Description Guidelines, Federal Register Vol. 66 No. 4, Friday January 5, 2001 "Notices", pages 1099-111.

Claims 1-13 and 15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a caryopsis-specific promoter of SEQ ID NO: 1 and caryopsis-specific functional portions comprising positions 2241 to 4683 and 4071 to 4683 of SEQ ID NO: 1 from wheat, does not reasonably provide enablement for any caryopsis-specific promoter comprising one or more of the sequence elements consisting of SEQ ID NOs: 2-10; or comprising any functional portion of the SEQ ID NO: 1; or a sequence having 60-99% sequence identity to SEQ ID NO: 1, or any sequence hybridizing thereto under unspecified conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Applicant broadly claims a caryopsis-specific promoter comprising one or more of the sequence elements consisting of SEQ ID NOs: 2-10; a caryopsis-specific promoter comprising any functional portion of the SEQ ID NO: 1; a caryopsis-specific promoter having 60-99% sequence identity to SEQ ID NO: 1; or a caryopsis-specific promoter of SEQ ID NO: 1 from wheat; or any promoter that hybridizes thereto under conditions of unspecified stringency, and a method of generating transgenic plants transformed with a caryopsis promoter, and the use of a caryopsis-specific promoter for caryopsis-specific expression in plants.

Applicant teaches a caryopsis-specific promoter of SEQ ID NO: 1 and functional portions of SEQ ID NO: 1 comprising positions 2241 to 4683 and 4071 to 4683 of SEQ ID NO: 1 from

wheat expressing GUS in the central endosperm of wheat seeds of transformed plants (Example 8 page 47).

Applicant does not teach a caryopsis-specific promoter comprising one or more of the sequence elements consisting of SEQ ID NOs: 2-10; a caryopsis-specific promoter comprising any functional portion of the SEQ ID NO: 1; or a caryopsis-specific promoter having 60-99% sequence identity to SEQ ID NO: 1.

The state of the art for the use of tissue specific homologous inter-functional 5' UTR regulatory gene sequences is unpredictable and is exemplified in the loss of heritable activity of a target gene regulated by a promoter inserted into a genome already containing a homologous endogenous copy of that promoter, and cannot be anticipated with any reasonable degree of predictability (Park Y. D. *et al.*, Plant Journal 1996, Feb. 9, (2): pp. 183-194, see Abstract).

Moreover, the identification of tissue specific gene expression or of phenotypic characteristics in plants by genetic transformation is highly unpredictable. The specific effects of given promoters on gene expression in transformed plants of different species using a promoter comprising any number of non-exemplified combinations of elements or degrees of sequence identity can not be anticipated with any reasonable degree of predictability and one of skill in the art must rely upon an empirical determination. The expression patterns conferred by specific combinations of 35S-subdomains differed in tobacco and petunia indicating that a combination of cis-regulatory elements may be interpreted differently in different species. (Benfey *et al.*, Science 250:959-966, 1990, see Abstract, lines 14-18 and page 966 column 1, lines 29-45).

Further, the expression of maize *adh-1* genes regulated in maize in an anaerobic fashion required additional non-endogenous enhancer sequences from the CaMV 35S enhancer or

upstream elements from the octopine synthase gene in order to function in tobacco (Ellis J. *et al.*, EMBO Journal, 1987, Vol. 6, no. 1, pp. 11-16; page 11 Abstract).

Another consideration in mixing specific elements for seed specific expression when engineering specific expression in a related species is the potential for changes in promoter *cis* elements that alter expression with respect to the species requirement for tissue specific regulation, or changes to *trans*-acting elements that could possibly eliminate tissue specific expression, in spite of the conservation of *cis*-acting elements between the orthologous sequences that regulate those genes (Matsuoka M. *et al.*, Plant Journal, 1994, Vol. 6, no. 3 pp. 311-319; page 317 column 1, lines 5-24 and column 2, lines 24-35).

Given the lack of guidance for isolating and identifying caryopsis specific promoters or functional portions comprising any number of non-exemplified sequence elements, the limited working examples in the specification that would exemplify combinations of caryopsis specific elements from a variety of non-exemplified sources, the breadth of the claims, and the unpredictability in the art, undue trial and error experimentation would have been required by one skilled in the art to evaluate a multitude of non-exemplified caryopsis-specific promoters.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 provides for the use of a nucleic acid molecule, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 13 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-2 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The DNA molecule, as claimed, has the same characteristics and utility as those found naturally in the genome or as cellular precursors thereof and therefore does not constitute patentable subject matter. See *American Wood v. Fiber Distintegrating Co.*, 90 U.S. 566 (1974), *American Fruit Growers v. Brogdex Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 (1980).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-13, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Robert L. et al., *Plant Cell*, December 1989, Vol. 1, pp. 569-578.

The claims broadly recite "a sequence which hybridizes with at least one of the nucleotide sequences stated under a)" under conditions of unspecified time, temperature, and salt concentration; and a "functional portion of the nucleic acid stated under a)" of unspecified length and activity.

Robert teaches endosperm specific expression of CAT in tobacco seeds, transformed with a wheat (monocot) high molecular weight glutenin caryopsis specific promoter, 8 days after anthesis (Abstract, lines 1-13 and page 573 column 2, lines 19-26), an expression cassette and vector, host cell, and transformed plants (page 570, column 1). Thus the reference teaches all the limitations of Claims 1-13, and 15.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Li Z., *et al.* Plant Physiology, August 1999, Vol. 120, pp. 1147-1155.

Li teaches the 5' untranslated region of a cDNA encoding a caryopsis specific class II starch synthase from wheat. Thus, the reference teaches all the limitations of Claims 1-2.

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (703) 305-5417. The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding, or if the examiner cannot be reached as indicated above, should be directed to the legal analyst, Gwendolyn Payne, whose telephone number is (703) 305-2475.

Russell Kallis Ph.D.
December 16, 2002

DAVID T. FOX
PRIMARY EXAMINER
GROUP 1638

Dec 16 2002